AMENDMENT TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than about 0.01%.
- 2. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than about 0.01%.
- 3. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than about 0.01%.

Claims 4-41 (canceled)

- 42. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than about 0.01% prepared by the process of:
 - a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- 43. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than about 0.01% prepared by the process of:
 - a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

- 44. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than about 0.01% prepared by the process of:
 - a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- 45. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0% and an exo-methylene content of less than about 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
 - a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- 46. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5% and an exo-methylene content of less than about 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
 - a) preparing a solution of ondansetron base in water;
 - b) acidifying the solution with hydrogen chloride to form a precipitate;
 - c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- 47. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9% and an exo-methylene content of less than about 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

- a) preparing a solution of ondansetron base in water;
- b) acidifying the solution with hydrogen chloride to form a precipitate;
- c) washing the precipitate; and
- d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.
- 48. (Previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the ondansetron base is prepared by the process of:
- a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula

N(Me)₂. HCl (where
$$R = C_{1-4}$$
, alkyl)

- b) heating the solution;
- c) removing a precipitate containing ondansetron base from the solution;
- d) washing the precipitate;
- e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

- 49. (Previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the crystallization step is performed only once.
- 50. (Previously presented) The pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as in claim 45, 46, or 47, wherein the ondansetron base is prepared by the process of:
- a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula

N(Me)₂. HC1 (where
$$R = C_{1-4}$$
, alkyl)

- b) heating the solution;
- c) removing a precipitate containing ondansetron base from the solution;
- d) washing the precipitate;
- e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

51. Cancelled.